

REMARKS

The applicants thank the Examiner for the telephone discussions regarding this application. Reconsideration of the rejections set forth in the Office action mailed December 12, 2005 is respectfully requested.

I. Amendments

The claims have been amended to recite definitions for the variables Pi and Pj in the structures shown in independent claims 28 and 41, as requested by the Examiner. (Applicants note that the structure was deleted from claim 38 in the previous amendment.) Support is found in the specification at, for example, page 8, lines 26-27, and in the sequence of SEQ ID NO: 1 itself.

No new matter is added by any of the amendments.

II. Information Disclosure Statement

The enclosed IDS includes copies of references provided in earlier responses to support arguments made by the applicants, and makes these references officially of record in the application. (Because these references have been known to the applicant for more than three months, they cannot be submitted under 37 CFR §1.97(d); therefore, an RCE accompanies this response, and the references are submitted under 37 CFR §1.97(a)(4).)

III. Interview Summary

Enclosed is an interview summary record in accordance with MPEP §713.04, summarizing the content and outcome of the discussions of January 11th and 17th, 2006.

It was agreed in the discussion of January 17th, 2006 that the present amendments would place the claims in condition for allowance.

IV. Pending Rejections under 35 U.S.C. §103(a)

The pending claims were rejected under 35 U.S.C. §103(a) as being unpatentable over Zalewski *et al.* (U.S. Patent No. 6,159,946) in view of Kobayashi *et al.* (*Osaka Daigaku*

Zasshi 47(6-12), Abstract, 1995), Summerton *et al.* (U.S. Patent No. 5,378,841), Agrawal *et al.* (U.S. Patent No. 5, 912,332), and Burger (WO 98/46740).

In the Office Action, the Examiner asserted that it would have been obvious at the time the invention was made, in view of these references, to carry out the claimed invention, and that the skilled person would have had a reasonable expectation of success.

The Examiner also pointed out, in the Office Action, that several of the references that had been submitted by the applicants to support a finding of unsuggested benefits (Roque, 2001, and Bult, July 2000, submitted with response of May 1, 2003; Gruberg, 2000, abstract submitted with response of December 16, 2003; and Kent, 2004, submitted with response of September 23, 2005), and the Kutryk *et al.* study (2002) described in the Weller Declaration (submitted with response of May 1, 2003), were published after the filing date of the application.

In the telephone conference of January 17th (see also enclosed Summary), it was agreed that efficacy of antirestenotic treatment in humans could in fact be considered an unsuggested benefit, even in view of effectiveness of the prior art treatment in an animal model (Zalewski *et al.*). As discussed in the responses of the dates noted above, and as supported by the enclosed articles, efficacy in animal models in this area had generally been found not to be reliably predictive of efficacy in humans. For example, the Gruberg review article, published in November 2000 and discussing the numerous studies and clinical trials dealing with restenosis, stated that "Despite intensive investigation in animal models and in clinical trials, most pharmacological agents have been found to be ineffective in preventing restenosis after percutaneous balloon angioplasty or stenting. Although studies frequently report success in the suppression of neointimal proliferation in animal models of balloon vascular injury, few of them have been successful in clinical trials."

It was further discussed in the telephone conferences of January 11th and 17th that the Kutryk *et al.* report discussed in the Weller Declaration, which showed that, in a clinical trial, the method and composition of Zalewski *et al.* did not effect restenosis rate or neointimal volume, was effective to establish nonoperability and/or lack of enablement of the Zalewski '946 patent with respect to inhibition of restenosis in human patients. (As stated by the Federal Circuit in *Beckman Instruments Inc. v. LKB Produkter AB* 892 F.2d

1547, 13 USPQ2d 1301, CAFC 1989, citing *In re Payne*, 606 F.2d 303, 203 USPQ 245, CCPA 1979: "In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method".) The fact that the Kutryk *et al.* report is dated after the filing date of the present invention does not negate this finding.

In view of the above, the applicants respectfully request that the pending rejections under 35 U.S.C. §103(a) be withdrawn.

V. Conclusion

In view of the foregoing, the applicant submits that the claims now pending are now in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would further expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4403.

Date: 1-20-2006


Correspondence Address:

PAYOR NUMBER 22918

PHONE: (650) 838-4403

Fax: (650) 838-4350

Respectfully submitted,



LeeAnn Gorthey
Registration No. 37,337